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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SEPRACOR INC. and UNIVERSITY OF MASSACHUSETTS, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD. Defendant.	Civil Action No.: 3:07-cv-04213-MLC-TJB **DEFENDANT SUN PHARMACEUTICAL INDUSTRIES LTD.'S ANSWER, AFFIRMATIVE DEFENSES, JURY DEMAND AND COUNTERCLAIMS**

Defendant Sun Pharmaceutical Industries Ltd. ("Sun"), by and through its undersigned attorneys, by way of Answer to the Complaint of Plaintiffs Sepracor Inc. ("Sepracor") and University of Massachusetts ("UMass"), states as follows:

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, arising from Defendant's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of the patented Clarinex® drug products prior to the expiration of the United States Patent Nos. 7,211,582 ("the '582 patent"), 7,214,683 ("the '683 patent") and 7,214,684 ("the '684 patent"), which are owned by Sepracor and UMass.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that Plaintiffs' complaint alleges infringement of the '582, '683 and '684 patents. Sun specifically denies that Plaintiffs are entitled to any relief pursuant to its Complaint. Sun is without information sufficient to form a belief as to the truth or falsity of the allegation regarding UMass' ownership of the '582, '683 and '684 patents, and therefore denies the same. On information and belief, Sun admits the faces of the '582, '683 and '684 patents list Sepracor as the assignee.

2. Plaintiff Sepracor is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

ANSWER: Sun is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

3. Plaintiff UMass is a public institution of higher education of the Commonwealth of Massachusetts, having a place of business at 55 Lake Avenue North, Worcester, Massachusetts 01655.

ANSWER: Sun is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

4. Upon information and belief, Sun is a corporation organized and existing under the laws of India, having a place of business at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai 400 059, India. Upon information and belief, Sun, through its wholly-owned subsidiary, Sun Pharmaceutical Industries Inc. ("Sun NJ"), leases a manufacturing facility at 270 Prospect Plains Road, Cranbury, NJ 08512, owns a facility at 6 Hollywood Court, South Plainfield, New Jersey 07080 and owns a manufacturing facility located at 1 Able Drive, Cranbury, NJ 08512. Sun NJ maintains a registered agent, Corporation Service Company, at 830 Bear Tavern Road, West Trenton, New Jersey 08628.

ANSWER: Sun admits that Sun is an Indian corporation having a place of business at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai 400 059, India. Answering further, Sun admits that its wholly owned subsidiary, Sun Pharmaceutical Industries, Inc. ("Sun USA"), a Michigan corporation, leases a manufacturing facility at 270 Prospect Plains

Road, Cranbury, NJ 08512, and owns a facility at 6 Hollywood Court, South Plainfield, New Jersey 07080. Sun admits that its subsidiary, Sun USA, maintains a registered agent, Corporation Service Company, at 830 Bear Tavern Road, West Trenton, NJ 08628. Sun denies that it owns a manufacturing facility located at 1 Able Drive, Cranbury, NJ 08512. Sun denies the remaining allegations of Paragraph 4, including any implications that Sun owns or leases property "through" its subsidiary.

5. Upon information and belief, Sun conducts business through and with its subsidiary, Sun NJ, which maintains a manufacturing facility at 1 Able Drive, Cranbury, NJ 08512.

ANSWER: Sun denies the allegations of Paragraph 5.

6. Upon information and belief, Sun is in the business of manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

ANSWER: Sun denies the allegations of Paragraph 6.

7. Upon information and belief, Sun assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j), ANDA No. 78-359 concerning generic versions of tablets containing 5 milligrams of Clarinex® brand desloratadine per tablet ("Sun's Proposed Product").

ANSWER: Sun admits that it filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. §355(j), ANDA No. 78-359 concerning a generic drug containing 5 milligrams desloratadine per tablet. Sun denies any implication that its ANDA product will contain Clarinex® brand desloratadine. Sun denies the remaining allegations of paragraph 7.

8. Upon information and belief, if ANDA No. 78-359 is approved, it is the intention of Sun to distribute Sun's Proposed Product in the United States.

ANSWER: Sun admits that if ANDA No. 78-359 is approved by the Food and Drug Administration, Sun intends to distribute its generic product in the United States. Sun denies any implication that its ANDA product will contain Clarinex® brand desloratadine.

Jurisdiction and Venue

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that this Court has subject matter jurisdiction as to the '582, '683 and '684 patents.

10. This court has personal jurisdiction over Sun. Upon information and belief, Sun is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun directly, or through its subsidiaries, agents and/or alter-egos (including Sun NJ), manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Sun purposefully has conducted and continues to conduct business, directly, and/or through its subsidiaries, agents and/or alter-egos (including Sun NJ) in this judicial district, and this judicial district is a likely destination of Sun's ANDA Product. Upon information and belief, Sun, through its subsidiaries, agents, and/or alter-egos (including Sun NJ) leases and owns facilities in this judicial district and retains a registered agent in this judicial district. Upon information and belief, Sun has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction. For example, Sun consented to jurisdiction in *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd.,* 07-cv-01516 and *PDL BioPharma, Inc. v. Sun Pharmaceutical Industries Ltd.,* 07-cv-01788; Sun admitted jurisdiction is proper in New Jersey in *Altana Pharma AG* v. *Sun Pharmaceutical Industries Ltd.,* 05-cv-3920; Sun participated in the New Jersey bankruptcy case, *Able Laboratories, Inc. and Estate of the Post-Confirmation Debtor,* 05-33129; and Sun filed a lawsuit against Altana Pharma AG in New Jersey, *Sun Pharmaceutical Industries Ltd.* v. *Altana Pharma AG et al.*, 05-cv-2391.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent that an answer is required, Sun denies that Sun USA -- Sun's wholly owned subsidiary -- is an agent or alter-ego of Sun. Sun further denies that it manufactures, markets, and sells generic drugs throughout the United States and in this judicial district through

Sun USA. Responding further, Sun consents to this Court's personal jurisdiction for purposes of the present litigation only. Sun denies the remaining allegations of Paragraph 10.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that venue is proper in this judicial district.

The Patents In Suit and the Clarinex® Drug Product

12. On May 1, 2007, the '582 patent, entitled "Methods for Treating Urticaria Using Descarboethoxyloratadine," was duly and legally issued. Sepracor and UMass are assignees of the entire right, title and interest in the '582 patent. A copy of the '582 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that the face of the '582 patent indicates that it is entitled "Methods for Treating Urticaria Using Descarboethoxyloratadine" and that the face of the '582 patent indicates that the patent was issued on May 1, 2007. Sun specifically denies that the '582 patent was duly and legally issued. Sun is without information sufficient to form a belief as to the truth or falsity of the allegation regarding the assignment of the '582 patent to UMass, and therefore denies the same. On information and belief, Sun admits the face of the '582 patent lists Sepracor as assignee of the '582 patent. Responding further, Sun admits that a copy of the '582 patent was attached as Exhibit A to the Complaint. Sun denies the remaining allegations of Paragraph 12.

13. On May 8, 2007, the '683 patent, entitled "Compositions of Descarboethoxyloratadine," was duly and legally issued. Sepracor and UMass are assignees of the entire right, title and interest in the '683 patent. A copy of the '683 patent is attached hereto as Exhibit B.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that the face of the '683 patent indicates that it is entitled "Compositions of Descarboethoxyloratadine" and that the face of the '683 patent indicates that the patent was issued on May 8, 2007. Sun specifically denies that the '683 patent was duly and legally issued. Sun is without information sufficient to form a belief as to the truth or falsity of the allegation regarding the assignment of the '683 patent to UMass, and therefore denies the same. On information and belief, Sun admits the face of the '683 patent lists Sepracor as assignee of the '683 patent. Responding further, Sun admits that a copy of the '683 patent was attached as Exhibit B to the Complaint. Sun denies the remaining allegations of Paragraph 13.

14. On May 8, 2007, the '684 patent, entitled "Methods for the Treatment of Allergic Rhinitis," was duly and legally issued. Sepracor and UMass are assignees of the entire right, title and interest in the '684 patent. A copy of the '684 patent is attached hereto as Exhibit C.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that the face of the '684 patent indicates that it is entitled "Methods for the Treatment of Allergic Rhinitis" and that the face of the '684 patent indicates that the patent was issued on May 8, 2007. Sun specifically denies that the '684 patent was duly and legally issued. Sun is without information sufficient to form a belief as to the truth or falsity of the allegation regarding the assignment of the '684 patent to UMass, and therefore denies the same. On information and belief, Sun admits the face of the '684 patent lists Sepracor as assignee of the '684 patent. Responding further, Sun admits that a copy of the '684 patent was attached as Exhibit C to the Complaint. Sun denies the remaining allegations of Paragraph 14.

15. The '582, '683 and '684 patents are identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" in association with 5 milligram desloratadine tablets, which are sold as a commercial product under the trade name Clarinex®. These patents cover approved uses of commercial Clarinex® and approved Clarinex® products.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits, upon information and belief, that the '582, '683 and '684 patents are identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations." Sun denies the remaining allegations of Paragraph 15.

Acts Giving Rise to this Action

16. Plaintiffs Sepracor and UMass received a letter from Sun, dated July 23, 2007 ("the Notification Letter"), notifying them that Defendant had filed with the FDA an ANDA (No. 78-359) under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale or sale of generic tablets containing 5 milligrams of Clarinex® brand desloratadine per tablet.

ANSWER: Sun admits that it sent Sepracor and UMass a Notice of Certification dated July 23, 2007 for Sun's ANDA No. 78-359 pursuant to 21 U.S.C. §§ 355(j)(2)(B)(i) and (ii), notifying Plaintiffs that Sun had filed ANDA No. 78-359 seeking to obtain FDA approval to engage in the commercial manufacture, use or sale of generic tablets containing 5 mg of desloratadine per tablet. Sun denies any implication that its ANDA product will contain Clarinex® brand desloratadine. Sun denies the remaining allegations of Paragraph 16.

17. Upon information and belief, Sun intends to engage and will engage in the commercial manufacture, importation, use, offer for sale or sale of Sun's Proposed Products promptly upon receiving FDA approval to do so.

ANSWER: Sun admits that it is seeking FDA approval to engage in the commercial manufacture, use or sale of a generic drug containing 5 mg desloratadine per tablet. Sun denies the remaining allegations of Paragraph 17.

18. The Notification Letter states that ANDA No. 78-359 contains a "Paragraph IV Certification" that, in Sun's opinion, the '582, '683 and '684 patents are invalid, unenforceable and/or not infringed.

ANSWER: Sun admits that its letter of July 23, 2007 contains a Paragraph IV Certification to its ANDA No. 78-359 alleging that the claims of the '582, '683 and '684 patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use or sale in the United States of the drug product described in Sun's ANDA.

19. The Notification Letter does not allege any basis for an allegation that the '582, '683.and '684 patents will not be infringed by the commercial manufacture, importation, use, offer for sale or sale of Sun's Proposed Products other than alleged invalidity.

ANSWER: Sun denies the allegations of Paragraph 19.

20. Upon information and belief, ANDA No. 78-359 contains information showing that Sun's Proposed Products (a) are bioequivalent to a patented Clarinex® 5 milligram tablet product; (b) have the same active ingredient as a patented Clarinex® 5 milligram tablet product; (c) have the same route of administration and strength as a patented Clarinex® 5 milligram tablet product; and (d) have the same, or substantially the same, proposed labeling, and the same indication and usage as a patented Clarinex® 5 milligram tablet product.

ANSWER: Sun specifically denies that the Clarinex® 5 milligram tablet product is "patented." Sun admits that ANDA No. 78-359 concerns a generic drug containing 5 mg desloratadine per tablet, and that ANDA No. 78-359 contains any required bioavailability and/or bioequivalence data from studies on the desloratadine tablet that is the subject of NDA 021165. Sun denies the remaining allegations of Paragraph 20.

21. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) before the expiration of forty-five days from the date of receipt of the Notification Letter.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that this action was brought within forty-five days of Sun's Notification Letter.

Count I – Infringement of the '582 Patent By Defendant

22. Plaintiffs repeat and reallege the allegations of paragraphs 1-21 as though fully set forth herein.

ANSWER: Sun repeats its answers to paragraphs 1-21 as though fully set forth herein.

23. Sun's submission of an ANDA including its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Sun's Proposed Products, prior to the expiration of the '582 patent, constitutes infringement of one or more of the claims of the '582 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Sun denies the allegations of Paragraph 23, including any implication that the '582 patent is valid and/or enforceable.

24. Unless enjoined by this Court, Sun, upon FDA approval of ANDA No. 78-359, will infringe the '582 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Sun's Proposed Products in the United States.

ANSWER: Sun denies the allegations of Paragraph 24, including any implication that the '582 patent is valid and/or enforceable.

25. Sun had notice of the '582 patent prior to undertaking its acts of infringement. Sun's infringement of the '582 patent has been, and continues to be, willful and deliberate.

ANSWER: Sun denies the allegations of Paragraph 25.

26. Plaintiffs will be substantially harmed if Sun's infringement of the '582 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

ANSWER: Sun denies the allegations of Paragraph 26.

Count II – Infringement of the '683 Patent By Defendant

27. Plaintiffs repeat and reallege the allegations of paragraphs 1-26 as though

fully set forth herein.

ANSWER: Sun repeats its answers to paragraphs 1-26 as though fully set forth herein.

28. Sun's submission of an ANDA including its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Sun's Proposed Products, prior to the expiration of the '683 patent, constitutes infringement of one or more of the claims of the '683 patent under 35 U.S.C. § 271 (e)(2)(A).

ANSWER: Sun denies the allegations of Paragraph 28, including any implication that the '683 patent is valid and/or enforceable.

29. Unless enjoined by this Court, Sun, upon FDA approval of ANDA No. 78-359, will infringe the '683 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Sun's Proposed Products in the United States.

ANSWER: Sun denies the allegations of Paragraph 29, including any implication that the '683 patent is valid and/or enforceable.

30. Sun had notice of the '683 patent prior to undertaking its acts of infringement. Sun's infringement of the '683 patent has been, and continues to be, willful and deliberate.

ANSWER: Sun denies the allegations of Paragraph 30.

31. Plaintiffs will be substantially harmed if Sun's infringement of the '683 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

ANSWER: Sun denies the allegations of Paragraph 31.

Count III – Infringement of the '684 Patent By Defendant

32. Plaintiffs repeat and reallege the allegations of paragraphs 1-31 as though fully set forth herein.

ANSWER: Sun repeats its answers to paragraphs 1-31 as though fully set forth herein.

33. Sun's submission of an ANDA including its § 505(j)(2)(A)(vii)(IV) certification to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Sun's Proposed Products, prior to the expiration of the '684 patent, constitutes

infringement of one or more of the claims of the '684 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Sun denies the allegations of Paragraph 33, including any implication that the '684 patent is valid and/or enforceable.

34. Unless enjoined by this Court, Sun, upon FDA approval of ANDA No. 78-359, will infringe the '684 patent under 35 U.S.C. § 271 by making, using, importing, offering to sell, or selling Sun's Proposed Products in the United States.

ANSWER: Sun denies the allegations of Paragraph 34, including any implication that the '684 patent is valid and/or enforceable.

35. Sun had notice of the '684 patent prior to undertaking its acts of infringement. Sun's infringement of the '684 patent has been, and continues to be, willful and deliberate.

ANSWER: Sun denies the allegations of Paragraph 35.

36. Plaintiffs will be substantially harmed if Sun's infringement of the '684 patent is not enjoined, and Plaintiffs are entitled to equitable relief.

ANSWER: Sun denies the allegations of Paragraph 36.

As to the Prayer for Relief, Sun denies that Plaintiffs are entitled to any of the relief requested in paragraphs (A) – (R), or to any relief whatsoever.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Non-Infringement of the '582, '683 and '684 Patents

The manufacture, use or sale of the product that is the subject of Sun's ANDA No. 78-359 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '582, '683 and'684 patents.

Second Affirmative Defense

Invalidity of the '582, '683 and '684 Patents

The claims of the '582, '683, and '684 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

Third Affirmative Defense

Additional Defenses

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

For their counterclaims against Plaintiffs Sepracor Inc. ("Sepracor") and University of Massachusetts ("UMass"), Defendant, Sun Pharmaceuticals Industries Ltd. ("Sun") states as follows:

Parties

1. On information and belief, Plaintiff Sepracor is a Delaware corporation having a place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

2. On information and belief, Plaintiff UMass is a public institution of higher education of the Commonwealth of Massachusetts, having a place of business at 55 Lake Avenue North, Worcester, Massachusetts 01655.

3. Sun is a corporation organized and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri Kurla Road, Andheri (East) Mumbai, 400 059, India.

Background

A. FDA Approval of New Brand-Name Drugs.

4. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve both brand-name and generic drugs.

5. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

6. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. §§ 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

7. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

B. Generic Competition – Abbreviated New Drug Applications ("ANDAs").

8. Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients as the brand-name drug.

9. Before 1984, a company that wished to make a generic version of an FDA-approved drug had to file an application containing new studies showing the already-

approved drug's safety and effectiveness. Preparing such an application was as time-consuming and costly as the original NDA.

10. In 1984, however, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments. See Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under the Hatch-Waxman Amendments, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

11. To receive approval of its ANDA, an applicant must show that its generic drug is "bioequivalent" to the listed reference drug. See 21 U.S.C. § 355(j)(4)(F).

12. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of the ANDA applicant's generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

13. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

14. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

15. Upon receiving notice of the paragraph IV certification, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

16. Patent holders have a significant strategic incentive to file suit because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

17. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, and/or not infringed, the FDA may approve the ANDA. *Id.*

C. Sun's Desloratadine ANDA.

18. Sun filed an ANDA (No. 78-359) with the FDA seeking generic approval for desloratadine tablets containing as the active ingredient desloratadine in 5 mg strength. The ANDA contains the required bioavailability and/or bioequivalence data from studies on the desloratadine tablet that is the subject of NDA 021165.

19. Because Sun seeks FDA approval to market its generic desloratadine tablets before expiration of the patents listed in the Orange Book, Sun's ANDA includes a paragraph IV certification to U.S. Patent Nos. 7,211,582 ("the '582 patent"), 7,214,683 ("the '683 patent") and 7,214,684 ("the '684 patent").

D. U.S. Patent Nos. 7,211,582, 7,214,683 and 7,214,684

20. The '582 patent was issued on May 1, 2007 to A.K. Gunnar Aberg, John R. McCullough and Emil R. Smith and assigned to Sepracor.

21. The ‘683 patent was issued on May 8, 2007 to A.K. Gunnar Aberg, John R. McCullough and Emil R. Smith and assigned to Sepracor.

22. The ‘684 patent was issued on May 8, 2007 to A.K. Gunnar Aberg, John R. McCullough and Emil R. Smith and assigned to Sepracor

23. The ‘582, ‘683 and ‘684 patents are listed in the Orange Book in connection with NDA No. 021165.

24. In order to have the ‘582, ‘683 and ‘684 patents listed in the Orange Book, the law required certification to the FDA, under oath, that the ‘582, ‘683 and ‘684 patents claim the “drug” desloratadine or a “method of using” desloratadine and are patents for which a claim of patent infringement could reasonably be asserted against an unauthorized party.

25. By bringing suit against Sun, Sepracor and UMass have taken active steps to block Sun’s attempt to launch generic 5 mg desloratadine tablets.

26. The claims of the ‘582, ‘683 and ‘684 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Sun’s 5 mg desloratadine tablets.

27. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Sun and Sepracor and UMass.

Jurisdiction and Venue

28. Sun realleges and incorporates by reference the allegations of Paragraphs 1-27 as if fully set forth herein.

29. Present, genuine, and justiciable controversies exist between Sun and Sepracor and UMass regarding the ‘582, ‘683 and ‘684 patents.

30. Subject matter jurisdiction over these counterclaims is proper under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

31. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

FIRST COUNT
(Declaration of Non-Infringement of the '582, '683 and '684 Patents)

32. Sun realleges and incorporates by reference the allegations of Paragraphs 1-31 as if fully set forth herein.

33. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '582, '683 and '684 patents will not be infringed by the manufacture, use or sale of Sun's 5 mg desloratadine tablets.

34. A present, genuine and justiciable controversy exists between Sun and Sepracor and UMass regarding, *inter alia*, the issue of whether the manufacture, use or sale of Sun's 5 mg desloratadine tablets would infringe the claims of the '582, '683 or '684 patents.

35. The manufacture, use or sale of Sun's 5 mg desloratadine tablets would not infringe any valid and/or enforceable claim of the '582, '683 or '684 patents.

36. Sun is entitled to a declaration that the manufacture, use or sale of Sun's 5 mg desloratadine tablets would not infringe any valid and/or enforceable claims of the '582, '683 and '684 patents.

SECOND COUNT
(Declaration of Invalidity of the '582, '683 and '684 Patents)

37. Sun realleges and incorporates by reference the allegations of Paragraphs 1-36 as if fully set forth herein.

38. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that claims of the '582, '683 and '684 patents are invalid.

39. A present, genuine and justiciable controversy exists between Sun and Sepracor and UMass regarding, *inter alia*, the validity of claims of the '582, '683 and '684 patents.

40. Claims of the '582, '683 and '684 patents are invalid under the provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

41. Sun is entitled to a declaration that claims of the '582, '683 and '684 patents are invalid.

REQUEST FOR RELIEF

WHEREFORE, Defendant, Sun Pharmaceutical Industries, Ltd. respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs, Sepracor and UMass as follows:

(a) declaring that Sun has not infringed any valid and enforceable claim of U.S. Patent Nos. 7,211,582, 7,214,683 and 7,214,684;

(b) declaring that claims of U.S. Patent Nos. 7,211,582, 7,214,683 and 7,214,684 are invalid;

(c) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Sun its attorneys' fees, costs and expenses in this action; and

(d) awarding Sun any further and additional relief as the Court deems just and proper.

WINSTON & STRAWN LLP
Attorneys for Defendant
Sun Pharmaceutical Industries, Ltd.

By: /s/ James S. Richter
James S. Richter

Dated: January 2, 2008

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JURY DEMAND

Defendant Sun Pharmaceutical Industries Ltd. requests a jury trial on all issues so triable.

WINSTON & STRAWN, LLP
Attorneys for Defendant

By: /s/ James S. Richter
James S. Richter

Dated: January 2, 2008

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, the undersigned counsel for Defendants Sun Pharmaceutical Industries Ltd. ("Sun") certifies that, to the best of his knowledge, information and belief, the matter in controversy is not the subject of any other action or proceeding, but is related to the following case, which is a patent infringement action involving the same plaintiffs

and one or more of the same three patents (United States Patent Nos. 7,211,582 ("the '582 patent", 7,214,683 ("the '683 patent"), and 7,214,684 ("the '684 patent")): *Sepracor Inc., et al. v. Glenmark Pharmaceuticals, Ltd., et al.*, Civil Action No. 07-33852 (SRC) (D.N.J.). Plaintiffs Sepracor Inc. and University of Massachusetts identified this related patent infringement action in their own Certifications pursuant to Local Rules 11.2 and 40.1.

The undersigned counsel for Sun additionally certifies that, to the best of his knowledge, information and belief, the following are also related patent infringement actions involving the same plaintiffs and one or more of the same three patents: (1) *Sepracor Inc., et al. v. Orchid Chemicals and Pharmaceuticals Ltd., et. al.*, Civil Action No. 07-04623 (MLC) (D.N.J.); (2) *Sepracor Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 07-5001 (FLW) (D.N.J.); (3) *Sepracor Inc., et al. v. Mylan Pharmaceuticals, Inc., et al.*, Civil Action No. 07-5017 (JAP) (D.N.J.); (4) *Sepracor Inc., et al. v. Perrigo Research and Development Company, et al.*, Civil Action No. 07-5136 (JAP) (D.N.J.); (5) *Sepracor Inc., et al. v. Lupin Limited, et al.*, Civil Action No. 07-5265 (JAP) (D.N.J.); (6) *Sepracor Inc., et al. v. Anchen Pharmaceuticals, Inc.*, Civil Action No. 07-5737 (FLW) (D.N.J.); (7) *Sepracor Inc., et al. v. Sandoz, Inc.*, Civil Action No. 07-6107 (MLC)(D.N.J.).

However, the following cases, identified by Plaintiffs in their Certifications pursuant to Local Rules 11.2 and 40.1, are not similarly related to the matter in controversy, because they do not involve the same plaintiffs or one or more of the same three patents: (1) *Schering Corporation v. Zydus Pharmaceuticals, USA, Inc., et al.*, Civil Action No. 06-4715 (MLC) (D.N.J.); (2) *Schering Corporation v. Caraco Pharmaceutical Laboratories Ltd., et al.*, Civil Action No. 06-14386 (E.D. Mich.); and (3) *Schering Corporation v. GeoPharma Inc., et al.*, Civil Action No. 06-1843 (M.D. Fla.), which have been consolidated before the Honorable Mary

L. Cooper under the caption, *In Re: Desloratadine Patent Litigation*, MDL No. 1851 (MLC) (D.N.J.).

/s/ James S. Richter
James S. Richter

Dated: January 2, 2008

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Sun Pharmaceutical Industries Ltd. hereby certifies that Sun's causes of action as asserted in its counterclaims seek primarily declaratory judgment relief. This action is, therefore, not appropriate for compulsory arbitration.

/s/ James S. Richter
James S. Richter

Dated: January 2, 2008

CERTIFICATE OF SERVICE

The undersigned attorney certifies that he caused a copy of the foregoing ANSWER, AFFIRMATIVE DEFENSES, JURY DEMAND AND COUNTERCLAIMS to be served by electronic mail on the 2nd day of January, 2008 upon:

Charles M. Lizza
Saul Ewing
One Riverfront Plaza
Newark, NJ 07102

/s/ James S. Richter
James S. Richter

Dated: January 2, 2008